IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
FLORENCE DIVISION

KELLI BAUGH and JUSTIN BAUGH,	)	
	)	**Civil Action No. 4:11-cv-00525-RBH**
Plaintiff(s),	)	
	)	
v.	)	
	)	
BAYER CORPORATION, BAYER HEALTHCARE, LLC, BAYER PHARMACEUTICALS CORPORATION, BAYER HEALTHCARE PHARMACEUTICALS, INC., BERLEX LABORATORIES, INC., and BERLEX, INC.,	)	
	)	
Defendants.	)	
	)	

DEFENDANT BAYER HEALTHCARE PHARMACEUTICALS, INC.'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT FOR LACK OF PROXIMATE CAUSE

Pursuant to Federal Rule of Civil Procedure 56(a), defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer") hereby files this Memorandum of Law in Support of Its Motion for Summary Judgment for Lack of Proximate Cause.

INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs Kelli and Justin Baugh claim that Bayer failed to adequately warn them that Ms. Baugh's Mirena® could perforate her uterus and migrate into her abdominal cavity, necessitating surgical removal and other complications. Plaintiffs' Complaint includes multiple counts but each is premised on the claim that Bayer failed to warn of risks associated with Mirena®.

South Carolina has adopted the learned intermediary doctrine, which requires that the manufacturer of a prescription product adequately warn the physician of the risks associated with

the product. Thus, to prevail on their failure–to–warn claim, plaintiffs must prove that Bayer's warning to the prescribing physician, Dr. Anu Chaudhry, was inadequate. Further, plaintiffs have the burden to establish that a different warning would have deterred Dr. Chaudhry from prescribing the product to Ms. Baugh. Plaintiffs have no evidence to support their claim.

On the contrary, Dr. Chaudhry testified that she was fully aware of the risk of perforation and migration when she prescribed Mirena® for Ms. Baugh in 2005. She learned about the risk as part of her medical training beginning in the 1980s. Moreover, Dr. Chaudhry testified that the risk of perforation and migration is common knowledge and well–known. This evidence refutes plaintiffs' failure–to–warn claim. As a result, plaintiffs cannot prove that Bayer proximately caused their alleged injuries. Thus, Bayer is entitled to summary judgment.

UNDISPUTED FACTS

Dr. Chaudhry inserted Ms. Baugh's Mirena® on November 1, 2005. *See* 9/10/12 Deposition Transcript of Anu Chaudhry, M.D. ("Chaudhry Dep.") at 126 (Ex. 1). Plaintiffs did not file suit until more than five years later on January 21, 2011. *See* 1/21/11 Compl., ECF No. 1-1. Plaintiffs brought the following causes of action for purported damages related to Ms. Baugh's use of Mirena®: (1) defective design, (2) negligence, (3) failure–to–warn, (4) strict liability, (5) breach of implied warranty, (6) personal injury, (7) breach of express warranty, (8) negligent misrepresentation, (9) fraudulent misrepresentation, (10) unfair trade practices, (11) fraud by concealment, and (12) loss of consortium. *See* Compl., ECF No. 1-1. In all these

causes of action, plaintiffs essentially allege that Bayer failed to warn of risks associated with Mirena®. *See, e.g., id.* at ¶¶ 24, 59, 64, 68, 84, 86, 91, 99, 103, 109, 115-116, 123, & 132.[1]

I. Mirena®

Mirena® is an intrauterine contraceptive device ("IUD") that contains a hormone called levonorgestrel. *See* 5/25/12 Deposition Transcript of L. William Goldstein, M.D. ("Goldstein Dep."), at 37 (Ex. 2). Mirena® does not require daily or pre–intercourse compliance, and it has a five–year lifespan. *See* Chaudhry Dep. at 39 & 42. Mirena® is among the most effective reversible contraceptives with a failure rate similar to or better than female sterilization. Goldstein Dep. at 39-42. The United States Food and Drug Administration ("FDA") approved Mirena® on December 6, 2000.[2] Mirena® is still on the market and has at all relevant times been an FDA-approved drug. *Id.*

II. Dr. Chaudhry Knew about the Risk of Perforation and Migration Before Inserting Ms. Baugh's Mirena®.

Dr. Chaudhry is a board-certified Obstetrician/Gynecologist practicing in Florence, South Carolina. Chaudhry Dep. at 7. Dr. Chaudhry went to medical school in India and received her initial medical training there. *Id.* at 55-56. In India, doctors prefer IUDs to birth control pills as a means of contraception for their patients. *Id.* at 43-44. Through her experience in India, Dr. Chaudhry became comfortable with IUDs. *Id.* at 43. Dr. Chaudhry testified that she learned of

[1] For instance, under their "Defective Design" cause of action, plaintiffs allege that Bayer "failed to disclose and warn of the health hazards and risks associated with the Mirena . . . ." *Id.* at ¶ 59. Under their "Negligent Misrepresentation" cause of action, by way of further example, plaintiffs allege that Bayer "concealed from Plaintiff Kelli Baugh and health care providers information about the propensity of Mirena to cause great harm." *Id.* at ¶ 109.

[2] *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails (FDA website with search link to FDA Mirena® information containing approval history) (last visited December 13, 2012).

the rare risk that an IUD may perforate the uterus and migrate into the abdominal cavity as part of her medical training as early as 1984. *Id.* at 50, 51 & 55-56. As part of her residency training in obstetrics and gynecology, she was taught how to remove an IUD that had migrated into the pelvis or the abdominal cavity. *Id.* at 54. After she immigrated to the United States, Dr. Chaudhry received additional training that reinforced her understanding that there was a risk of perforation and migration with IUD products. *Id.* at 56.

Dr. Chaudhry testified that "it was common knowledge" that IUDs can perforate the uterus. *Id.* at 51-54. She advised that the risk of perforation and migration is discussed in the peer-reviewed medical literature. *Id.* at 54. She acknowledged that the risk is "well-known." *Id.* Importantly, she testified that she knew that Mirena® could perforate the uterus and migrate into the abdominal cavity before she prescribed Ms. Baugh Mirena®. *Id.* at 50-54.

Dr. Chaudhry continues to prescribe Mirena®. *Id.* at 44. She believes that Mirena® is better than the other IUD product available in the United States. *Id.* at 63.

SUMMARY JUDGMENT STANDARD

A motion for summary judgment pursuant to Rule 56(a) is granted where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." *Moss v. City of Abbeville*, 740 F. Supp. 2d 738, 743 (D.S.C. 2010) (citation omitted) (J. Harwell). Once the movant shows that summary judgment is appropriate, "the opposing party must respond to the motion with 'specific facts showing a genuine issue for trial.'" *Id.* (citation omitted).[3]

[3] In 2010, Federal Rules of Civil Procedure Rule 56 was revised. F.R.C.P. Rule 56(c) became F.R.C.P. Rule 56(a). The only change to the language was that genuine "issue" became genuine "dispute".

The non-movant "must come forward with some evidence beyond the mere allegations contained in the pleadings to show that there is a genuine issue for trial." *Id.* (citation omitted). A non-movant's "beliefs, conjecture, speculation, or conclusory allegations" cannot "defeat a motion for summary judgment." *Id.* ("Rather, the nonmoving party is required to submit evidence of specific facts by way of affidavits, depositions, interrogatories, or admissions to demonstrate the existence of a genuine and material factual issue for trial.") (citations omitted).

Although facts and inferences "must be viewed in the light most favorable to the non-moving party," the "mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment. The requirement is that there be no *genuine* issue of *material* fact." *Id.* (citations omitted) (emphasis in original).

ARGUMENT

I. Each of Plaintiff's Claims Is Premised on a Failure–to–Warn Theory and Subject to the Learned Intermediary Doctrine.

All of plaintiffs' claims are premised on an alleged failure to provide adequate warnings about the risks of Mirena®. More specifically, each cause of action alleges that Bayer either failed to adequately disclose the risks associated with Mirena® or misrepresented the risks associated with Mirena®. *See Supra*, Undisputed Facts.

II. Plaintiffs' Claims Fail under the Learned Intermediary Doctrine.

In South Carolina, a prescription product "manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient." *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (applying South Carolina law). This duty, known as the learned intermediary doctrine, "is based upon the principle that a prescribing physician 'is in the best position to understand the patient's needs and assess the

risks and benefits of a particular course of treatment.'" *Sauls v. Wyeth Pharms., Inc.*, 846 F. Supp. 2d 499, 502 (D.S.C. 2012) (citation omitted) (applying South Carolina law).

The learned intermediary doctrine applies to causes of action premised on an alleged failure–to–warn, regardless of the legal theory on which plaintiffs rely. *See id.* (applying learned intermediary to negligence and strict liability claims) (citation omitted); *see also Weston v. Kim's Dollar Store*, 731 S.E.2d 864, 866 (S.C. 2012) (noting that plaintiff's causes of action for, *inter alia*, breach of implied warranty, unfair trade practices, and strict liability "[e]ssentially" fell under a failure–to–warn theory). *See generally Talley v. Danek Medical, Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (affirming district court ruling that "breach of warranty and fraud claims" were "essentially" failure–to–warn claims subject to the learned intermediary doctrine) (applying Virginia law) (citations omitted); *see also generally Couick v. Wyeth, Inc.*, 691 F. Supp. 2d 643, 645 (W.D.N.C. 2010) (holding plaintiff's claims were "based on the premise that [defendants] . . . failed to adequately warn" thus "[w]hile the plaintiff's claims [we]re masked in various legal theories, they are premised on a single claim of product liability.") (applying North Carolina law); *In re Norplant Contraceptive Prods. Liability Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997) (holding "gravamen . . . of Plaintiffs' causes of action" was an alleged failure–to–warn thus "the learned intermediary doctrine applie[d] to all of Plaintiffs' causes of action") (applying Texas law).

In order to prevail in a failure–to–warn case, plaintiffs must prove that the alleged failure–to–warn was the proximate cause of plaintiff's injuries. Specifically, in a case involving the learned intermediary doctrine, plaintiffs must show that "an adequate warning" would have deterred the physician from prescribing the product. *Odom*, 979 F.2d at 1003 (noting plaintiffs must show that a different warning "'would have changed the treating physician's decision to

prescribe the product for the plaintiff'") (citation omitted); *see also Sauls*, 846 F. Supp. 2d at 502 (noting plaintiff "must also establish that the inadequacy of the warning was the proximate cause of the plaintiff's injury"). Plaintiffs, however, "cannot" prove causation if the prescribing physician "already knew of the medical risk." *Odom*, 979 F.2d at 1003 (citing *Stanback v. Parke, Davis and Co.*, 657 F.2d 642, 645 (4th Cir. 1981) (affirming grant of summary judgment where doctor "testified in his deposition that he knew of the risk . . . at the time he vaccinated") (applying Virginia law)). Nor can plaintiffs ask the Court to "presume causation." *Odom*, 979 F.2d at 1003 (noting "no such presumption [exists] under South Carolina law"). Instead, plaintiffs have the burden to show that information about a non-disclosed risk was sufficiently important that it would have changed the treating physician's decision to prescribe the product. *Id.*

Here, plaintiffs cannot meet their burden. Their failure–to–warn claims fail for two independent reasons: (1) there was no "non-disclosed risk" – Dr. Chaudhry was fully aware of the risk of perforation and migration with Mirena® prior to prescribing Ms. Baugh's Mirena® and (2) plaintiffs have no evidence that different or additional warnings would have changed Dr. Chaudhry's prescribing decision.

a. Plaintiffs cannot establish proximate cause because Dr. Chaudhry was independently aware of the risk of uterine perforation and migration.

In South Carolina, a physician's pre-existing knowledge of a medical risk breaks the causal chain in failure–to–warn cases. *See Odom*, 979 F.2d at 1003 ("[T]he manufacturer cannot be said to have caused the injury if the doctor already knew of the medical risk"). In this case, Dr. Chaudhry was already aware of the risk of uterine perforation and migration prior to prescribing Mirena® for Ms. Baugh. As the Fourth Circuit explained in *Odom*, this already–existing knowledge slams the door on plaintiffs' claims.

In *Odom*, plaintiff alleged that the "Copper-7" IUD caused her to have an ectopic pregnancy secondary to pelvic inflammatory disease ("PID"), which she claimed was caused by her IUD. *Odom*, 979 F.2d at 1002. Plaintiff asserted that the manufacturer of the Copper-7 failed to adequately warn of the risks of PID and ectopic pregnancy. *Id.* The facts established that the prescribing physician was fully knowledgeable about the risks of both PID and ectopic pregnancy with IUDs from his medical school training, as well as from his review of medical literature. *Id.* at 1003. In light of this knowledge, the Fourth Circuit affirmed the trial court's conclusion that the treating physician "would have prescribed the CU-7 no matter how carefully [the manufacturer] refined the phrasing of the warning." *Id*.

The facts of *Odom* closely parallel the facts here and compel a similar legal conclusion. For example,

- Mrs. Odom's doctor had an "independent knowledge of the risk of PID." *Odom*, 979 F.2d at 1003 (noting Mrs. Odom's treating physician testified that "he already knew of the risk of PID through his own experience and training").
    - Dr. Chaudhry had an independent knowledge of the risk of perforation and migration and that an intra-abdominal IUD would need to be surgically removed. *See* Chaudhry Dep. at 50-56.
- Mrs. Odom's doctor testified that the risk of PID was "common knowledge." *Odom*, 979 F.2d at 1003.
    - Dr. Chaudhry testified that the risk of perforation and migration was "common knowledge." Chaudhry Dep. at 51-54.
- Mrs. Odom's doctor testified that "[m]edical literature" discussed the risk of PID. *Odom*, 979 F.2d at 1003.
    - Dr. Chaudhry testified that medical literature discussed the risk of perforation and migration. *See* Chaudhry Dep. at 54-55
- Mrs. Odom's doctor testified that "it was common medical school knowledge that PID could lead to ectopic pregnancy." *Odom*, 979 F.2d at 1003.

- Similarly, Dr. Chaudhry testified that medical schools on two continents educated her about the risk of perforation and migration. *See* Chaudhry Dep. at 55-56.

As in *Odom*, the facts in the present case clearly establish that Dr. Chaudhry had pre–existing knowledge of the risk of perforation of the uterus and migration of Mirena® into the abdominal cavity prior to prescribing the device for plaintiff. *See Odom*, 979 F.2d at 1003; *see also Anderson v. Green Bull, Inc.*, 471 S.E.2d 708, 710 (S.C. Ct. App. 1996) ("[S]eller is not required to warn of dangers or potential dangers that are generally known and recognized.") (citations omitted). This knowledge did not alter Dr. Chaudhry's judgment that Mirena® was an appropriate contraceptive for Ms. Baugh. *See* Chaudhry Dep. at 132-33. Accordingly, as in *Odom*, this court should find that plaintiffs have failed to carry their burden and that Bayer is entitled to summary judgment.

b. Plaintiffs cannot establish proximate cause because they have no evidence that Dr. Chaudhry would have changed her prescribing decision.

Plaintiffs' claims fail for the additional reason that they have no evidence that different or additional warnings would have changed Dr. Chaudhry's prescribing decision. South Carolina does not recognize a heeding presumption in failure–to–warn cases. Instead, "the burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Odom*, 979 F.2d at 1003.

Here, plaintiffs deposed Dr. Chaudhry but failed to elicit testimony that Dr. Chaudhry would have chosen not to prescribe Mirena® for Ms. Baugh given different or additional

warnings.[4] In the absence of such evidence, plaintiffs cannot carry their burden of establishing proximate cause, and summary judgment is appropriate. *See Sauls*, 846 F. Supp. 2d at 503 (granting summary judgment after noting that "[n]umerous courts have concluded that a plaintiff fails to carry her burden in establishing proximate cause in the absence of any evidence demonstrating how an adequate warning would have altered a physician's prescription decision.").

CONCLUSION

For the reasons set forth above, plaintiffs cannot meet their burden to establish that Bayer proximately caused their alleged injuries. Bayer requests that the Court grant its Motion for Summary Judgment pursuant to Rule 56(a).

Respectfully submitted,

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[4] To the contrary, Dr. Chaudhry testified that she knew about the risk of perforation and migration, continues to prescribe Mirena®, and believes it is the best IUD on the market. *See* Chaudhry Dep. at 44, 50, 55-56, & 63.